

K082830

OCT 10 2008

Toshiba America Medical Systems, Inc.
Pre-Market Notification 510(k) for INFX-8000H

510(k) Summary

Date: September 16, 2008

Submitter's Name: Toshiba America Medical Systems, Inc.

Submitter's Address: P.O. Box 2068, 2441 Michelle Drive,
Tustin, CA 92781-2068

Submitter's Contact: Paul Biggins, Director Regulatory Affairs
(714)730-5000

Establishment Registration Number: 2020563

Device Proprietary Name: INFX-8000H (Infinix-i)

Common Name: Electrostatic Fluoroscopic x-ray System
[Fed. Reg. No. 892.1650, Pro. Code: 90MQB]

Regulatory Class: II (per 21 CFR 892.1650)

Performance Standard: 21 CFR Subchapter J,
Federal Diagnostic X-ray Equipment Standard

Predicate Device(s): Toshiba INFX-8000C [k081621]

Reason For Submission Addition of new x-ray table and model change

Description of this Device:

This system is a single system that employs x-rays to obtain fluoroscopy or radiography images of the body. The system is comprised of a computer system, support arms (that contain the tube and solid state detector), x-ray generator and a patient table.

Summary of Intended Uses:

This device is a digital x-ray system configured for use as a diagnostic x-ray angiography system. This x-ray angiography system is used for diagnostic and interventional procedures for cardiac blood vessels, cerebral blood vessels, abdominal blood vessels and lower extremities.

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Technological Characteristics:

This device employs similar materials and processes as found in the predicate device. The device produces ionizing radiation that is employed to generate fluoroscopic and radiographic images of the anatomy.

Safety and Effectiveness Concerns:

This device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820. All requirements of the Federal Diagnostic Equipment Standard, as outlined in 21 CFR § 1020, that apply to this device, will be met and reported via an initial report. Additionally this system is in conformance with the applicable parts of the IEC 60601-1 {applicable portions}; IEC 60601-2-32, and IEC 60601-2-28. - Medical Device Safety standards.

Substantial Equivalence:

The INFX-8000H is of comparable type and substantially equivalent to:

Toshiba INFX-8000C; 510(k) Control # K081621

Therefore the INFX-8000H complies with the same or equivalent standards and has the same intended use as the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Toshiba America Medical Systems, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
BUFFALO MN 55313

AUG 21 2013

Re: K082830

Trade/Device Name: INFX-8000H; Infiniti-i
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA, MQB, and IZI
Dated: September 25, 2008
Received: September 26, 2008

Dear Mr. Job:

This letter corrects our substantially equivalent letter of October 10, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

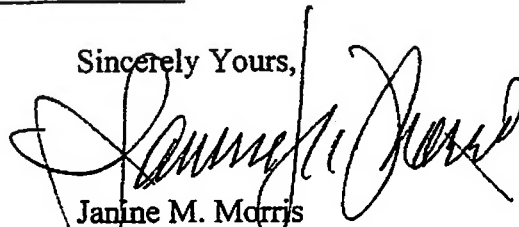
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,

A handwritten signature in black ink, appearing to read 'Janine M. Morris', is written over the typed name and title.

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Toshiba America Medical Systems, Inc.
Pre-Market Notification 510(k) for INFX-8000H

Indications for Use

510(k) Number (if known): K092830

Device Name: INFX-8000H; Infinix-i

Indications for Use:

This device is a digital radiography/fluoroscopy system used in a diagnostic angiography configuration. This system is indicated for use in diagnostic and angiographic procedures for blood vessels in the heart, brain, abdomen and lower extremities.

Prescription Use X
(Part 21 CFR 801 Subpart D)

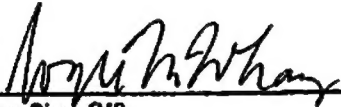
AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of _____


(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K092830